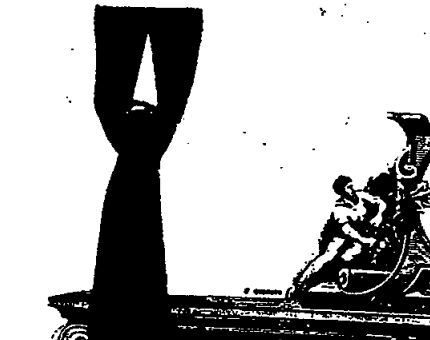
10



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

September 22, 1997

IS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS
THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

PLICATION NUMBER: *07/494,804*
ING DATE: *March 14, 1990*
ENT NUMBER: *5,068,249*
UE DATE: *November 26, 1991*
LE OF INVENTION:
EOUS RANITIDINE COMPOSITIONS STABILIZED WITH ETHANOL
NTOR(S):
G, DAVID R.

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

K. White

K. WHITE
Certifying Officer

CLAIMS

1. A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing ethanol.

2. A pharmaceutical composition according to claim 1 containing 2.5% to 10% weight/volume ethanol based on the complete formulation.

3. A pharmaceutical composition according to claim 1 containing 7% to 8% weight/volume ethanol based on the complete formulation.

4. A pharmaceutical composition according to claim 1 having a pH in the range 6.5 to 7.5.

5. A pharmaceutical composition according to claim 1 having a pH in the range 6.8 to 7.4.

6. A pharmaceutical composition according to claim 1 having a pH in the range 7.0 to 7.3.

7. A pharmaceutical composition according to claim 1 wherein said pH is obtained by the use of buffer salts.

8. A pharmaceutical composition as claimed in claim 1 suitable for oral administration.

9. A pharmaceutical composition as claimed in claim 8 containing 20-400 mg ranitidine per 10 ml dose expressed as free base.

10. A pharmaceutical composition according to claim 8 containing 20-200 mg ranitidine per 10 ml dose expressed as free base.

11. A pharmaceutical composition according to claim 8 containing 150 mg ranitidine per 10 ml dose expressed as free base.

~~12.~~ 7 A pharmaceutical composition according to claim 1 prepared using ranitidine in the form of the hydrochloride salt.

~~13.~~ 11 A pharmaceutical composition which is an aqueous formulation of ranitidine suitable for oral administration containing 150 mg ranitidine per 10 ml dose expressed as free base, said formulation having a pH in the range 7.0 to 7.3 and also containing 7% to 8% weight/volume ethanol based on the complete formulation.

~~14.~~ 12 A pharmaceutical composition according to claim ~~13~~ 11 wherein said pH is obtained by the use of buffer salts.

Add D7

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Also containing ethanol (claim 1) is indefinite as to whatelse is included. The claims should state how the pH is arrived at.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accord with the entire disclosure. See MPEP 706.03(n) and 706.03(z).

All claims should recite amounts for all ingredients.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (e) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

person or subject to an obligation of assignment to the same person.

Claims 1-14 are rejected under 35 U.S.C. 103 as being unpatentable over Chem. Absts. all.

The art teaches the cojoined use of use of ranitidine and an alcohol (ethanol). The claims also teach ranitidine and ethanol. The various parameters of the claims; i.e. pH and amounts are considered as choices to one skilled in the art. Such parameters have not been demonstrated as being critical and as such are considered to be within the skill of the art.

All of the claims are rejected over the claims of Serial No. 131,42 on the grounds of double patenting (35 USC 101). No second invention is seen to residue in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Standley Friedman whose telephone number is (703) 557-9592.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3920.

06/26/89;rbb

Stanley J. Friedman
Primary Examiner
Group Art Unit 12[illegible]

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AND DISCARD CARBON

FORM PTO-892 (REV. 3-78) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
344,620 1,494,804	125	3

APPLICANT(S): Long

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A						
	B						
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

X R Chem. Abst. (97) – 61014G (1982).

X S Chem. Abst. (104) – 102280 Z (1986).

T

U

EXAMINER	DATE	
FRIEDMAN	6/12/89	(X) = in parent.

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

David R. LONG

Serial No.: 07/344,620 Group Art Unit: 125

Filed: April 28, 1989 Examiner: Friedman

For: PHARMACEUTICAL COMPOSITIONS

AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the Official Action of June 28, 1989 in connection with the above-identified application. The period for response to the Official Action has been extended to expire on October 28, 1989 by the filing herewith of a Petition for a one-month extension of time and payment of the required fee.

Please amend the above-identified application as follows:

IN THE CLAIMS

Please amend claim 1 as follows:

1. (Amended) A pharmaceutical composition which is an aqueous formulation for oral administration, an effective amount of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation ~~also containing~~ comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

Please cancel claim 4 without prejudice or disclaimer.

REMARKS

Applicant has amended the claims as in the parent application in order to more particularly define the invention. The same 112 rejection was dropped in the parent application in view of these amendments.

More particularly, claims 1 and 4 have been combined and the amount of ethanol present has been functionally defined. Claim 4 has been cancelled from the application. The claims remaining in the application are Claims 1-3 and 5-10. Applicant most respectfully submits that all the claims now present in the application are in full compliance with 35 USC 112 and are clearly patentable over the references of record.

The rejection of Claims 1-10 under 35 USC 112 second paragraph as being indefinite has been carefully considered. The expression "also containing ethanol" has been modified to specify that the amount of ethanol contained in the composition is a stabilizing amount of ethanol and this amendment is fully supported by applicant's specification, at page 2, lines 4 and 5.

In addition, the pH range from Claim 4 has been included in Claim 1. Applicant most respectfully submits that there is no requirement that the method of obtaining the pH be set forth in the claims. This would be fully appreciated by one of ordinary skill in the art. In fact, the desired pH can be simply achieved by adding an appropriate amount of a

physiologically acceptable acid or base to the solution, depending on whether the solution is prepared from ranitidine free base or an acid addition salt thereof. It is not necessary to use buffer salts to obtain the desired pH, although it may often be more convenient to do so. Accordingly, it can be seen that the means for adjusting pH are entirely conventional and therefore, it is most respectfully requested that this aspect of the rejection under 35 USC 112 be withdrawn. As far as Claim 7 is concerned, having inserted the pH range in Claim 1, the amount of buffer salts is thereby predetermined, depending on the specific buffer salts that are used.

The rejections of Claims 1-14 under 35 USC 103 as being unpatentable over Chemical Abstract has been carefully considered. In the Official Action it is urged that the art teaches the cojoining of ranitidine and an alcohol; e.g., ethanol. The addition of a non-critical pH limitation and non-critical amounts are not seen as patentable limitations to the various claims. This rejection having been carefully considered is most respectfully traversed.

At the outset, applicant specifically traverses the statement in the Official Action that the references relied upon by the Examiner teach the cojoining of ranitidine and an alcohol, e.g., ethanol. Applicant most respectfully submits that the art does not teach the cojoining of ranitidine and an alcohol in a pharmaceutical composition which is an aqueous formulation for oral administration. These references do not lead one of ordinary skill in the art any way to expect that

the stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of ethanol and does not suggest the presence of ethanol in such compositions.

The first Chemical Abstract reference (97 61014G) relates to the Glaxo patent for a new polymorphic form of ranitidine hydrochloride (designated form 2) and includes a description of processes for its production. Applicant most respectfully submits that all that one of ordinary skill in the art can infer from this reference is that ranitidine hydrochloride must be reasonably stable in ethanol since ethanol is used as a solvent for recrystallization. However, there is no teaching whatever that the stability of ranitidine or its salts as an aqueous formulation for oral administration is enhanced by the presence of ethanol and no suggestion that ethanol should be included in pharmaceutical formulations containing ranitidine as presently claimed.

The second Chemical Abstract reference (104 102280z) relates to a paper in a Scandinavian journal indicating the presence of ethanol in a person's diet did not adversely effect the gastric acid secretion inhibiting properties of ranitidine. Again, there is absolutely no teaching in this reference that would lead one of ordinary skill in the art to expect that ethanol would enhance the stability of ranitidine in aqueous oral formulations or would suggest to one of ordinary skill in the art that ethanol should be added to such formulations.

In summary, the prior art relied upon in the rejection is in fact, extremely far removed from the present claimed

invention and no way renders it obvious. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicant wishes to reiterate that the stability of a pharmaceutical formulation for oral administration is the most important factor and enhancing the stability of the active ingredient of such formulations is always an objective. Thus, in the development of any pharmaceutical formulation, it is necessary to ensure that the drug substance is stable within the formulation and this is necessary for two main reasons. Firstly, the drug substance must be stable in order to ensure that the patient is receiving the correct dosage of the drug. Secondly, it is important to ensure that the patient is not receiving significant amounts of breakdown products arising from the degradation of the drug substance in the formulation. This second point is particularly important since it is not always possible to identify fully all of the breakdown products that may occur. Consequently, the chronic toxicity of all of the various compounds arising from the breakdown of the drug substance cannot be determined.

In practice, degradation of the drug substance within a formulation usually occurs upon storage and is often dependent upon a number of factors including temperature and time of storage. Any improvement that can be made in enhancing the stability of the drug substance can only benefit the patient since it ensures more accurate dosage and the intake of less breakdown products. In addition, enhancement of the stability of the drug substances also benefit from the economic point of view in that it increases the effective shelf life of the

product. There is not the remotest suggestion of this in the prior art of record.

Applicant would like to make of record an additional reference which has only recently come to the attention of applicant when the corresponding German specification was cited in connection with the corresponding application is Austria. This is UK Patent Application No. 2,120,938A. This specification relates to the combination of anti-ulcer drugs such as ranitidine together with salicylic acid or a salt thereof and optionally a non-steroidal anti-inflammatory. Page 7, lines 20-29 of this document refers to the formulations for parenteral administration and states that these may be formulated in water or organic solvents including a reference to lower aliphatic alcohols, optionally in admixture with water. However, there is absolutely no teaching which would lead one of ordinary skill in the art to select ethanol in combination with ranitidine in the expectation of providing an oral formulation which is stabilized by the presence of ethanol. Thus, this reference neither alone or in combination with any other reference anticipates or renders obvious the presently claimed invention.

In view of the above comments and amendments to the claims, favorable reconsideration and allowance of all of the

Claims now present in the application are most respectfully requested.

Respectfully submitted,

Richard E. Fichter
Registration No. 26,382

BACON & THOMAS
625 Slaters Lane - Fourth Floor
Alexandria, Virginia 22314
(703) 683-0500

Date: October 30, 1989

part

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Sheet 1 of 1

ATTY. DOCKET NO.	SERIAL NO.
REF/Long/620	07/344,620

APPLICANT: David R. LONG

FILING DATE	GROUP
4/28/89	125

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
2120938A	5/83	United Kingdom				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER: [signature] DATE CONSIDERED 11/11/97

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

07/344,038—04/28/89 LUKE

REF/Hall07

RICHARD E. FICHTER
BACON & THOMAS
625 SLATERS LANE, FOURTH FLOOR
ALEXANDRIA, VA 22314

FRIEDMAN, S

125 6

11/14/89

☐ This application has been examined ☐ Responsive to communication filed on 10/30/89 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Art Cited by Applicant, PTO-1449.
3. ☐ Information on How to Effect Drawing Changes, PTO-1474.
4. ☐ Notice re Patent Drawing, PTO-948.
5. ☐ Notice of Informal Patent Application, Form PTO-152.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-3 + 5-14 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims all are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

44

PTOL-326 (Rev. 6-88) EXAMINER'S ACTION

Claims 1-3 and 5-10 remain rejected under the 2nd paragraph for the reasons of record. The presence of "also" (claim 1) leaves open the question what other ingredients might be intended.

Claims 1-3 and 5-10 remain rejected under 35 USC 112, 1st paragraph for the reasons of record. The claims are silent as to the amount of ranitidine present. It is 10 grams, 5 mg., an effective amount or what? We don't know. Page 3 states an amount. The claims are broader than this.

All claims remain rejected under 35 USC 103 for the reasons clearly of record. Chem. Abst. 104 clearly shows ranitidine administered in the presence of ETOH and obviously the mixture is aqueous. Chem. Abst. 97- shows ranitidine with an alcohol (2-propanol). This art clearly precludes applicants claims to ranitidine and ETOH. (A) 104- teaches the ingredients together in the presence of each other. (B) 97- does show an alcohol and ranitidine in a formulation. As for the allegation of enhanced stability, it has not been demonstrated for the compositions urged as contrasted with any of other pH parameters.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

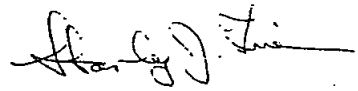
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE (3) MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO (2) MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE (3) MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX (6) MONTHS FROM THE DATE OF THIS FINAL ACTION.

FRIEDMAN:cwh

A/C 703

557-3920

11-13-89



...ley J. Friedman
...imary Examiner
...n Art Unit ...

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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07/49-1904

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S/C

JH

4/26/4

REQUEST FOR FILING FILE WRAPPER CONTINUATION APPLICATION UNDER 37 C.F.R. 1.62

Honorable Commissioner of
Patents and Trademarks
Box FWC
Washington, D.C. 20231

Sir:

This is a request for filing a FILE WRAPPER CONTINUATION under 37 C.F.R. 1.62 of pending prior application:

SERIAL NO.: 07/344,620 GROUP ART UNIT: 125

FILED: April 28, 1989 EXAMINER: Friedman

INVENTOR: LONG

TITLE: PHARMACEUTICAL COMPOSITIONS

by the following inventors:

Full Name of Inventor: David Richard Long
Residence: 41, Echo Hill
City: Royston, Hertfordshire
State or Country: ENGLAND

Full Name of Inventor:
Residence:
City:
State or Country:

Full Name of Inventor:
Residence:
City:
State or Country:

82

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/[illegible]304	05/14/90	LONG, D.	

RICHARD E. FICHTER
BACON & THOMAS
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER
FRIEDMAN, S

ART UNIT	PAPER NUMBER
125	9

DATE MAILED: 05/04/90

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-3+5-4 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims all are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

53

PTOL-326 (Rev. 9-89) EXAMINER'S ACTION

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Also containing ethanol (claim 1) is indefinite as to what else is included. The claims should state how the pH is arrived at.

Claims 1-3 and 5-12 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accord with the entire disclosure. See MPEP 706.03(n) and 706.03(z).

All claims should recite amounts for all ingredients.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

54

All claims are rejected under 35 U.S.C. 103 as being unpatentable over Chem. Absts. all.

The art teaches the cojoined use of use of ranitidine and an alcohol (ethanol). The claims also teach ranitidine and ethanol. The various parameters of the claims; i.e. pH and amounts are considered as choices to one skilled in the art. Such parameters have not been demonstrated as being critical and as such are considered to be within the skill of the art.

All of the claims are rejected over the claims of Serial No. 131,422 on the grounds of double patenting (35 USC 101). No second invention is seen to residue in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Friedman whose telephone number is (703) 557-9592.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 557-3920.

04/30/90;dal

Stanley J. Friedman
Primary Examiner
Group Art Unit 125

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11/21 JRP 11/21/90

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LONG

Serial No. 07/494,804

Filed: March 14, 1990

For: PHARMACEUTICAL COMPOSITIONS

Examiner: Friedman, S.

Group Art Unit: 125

AMENDMENT

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the Official Action dated May 4, 1990, the period for response to which has been extended to expire on November 4, 1990, by the filing herewith of a Petition for a three month extension of time and and payment of the required fee. Please amend the above-identified application as follows.

IN THE CLAIMS:

Claim 1, line 2, before 'of ranitidine' please insert --an effective amount--;

Line 4, please delete "also containing" and insert --comprising--.

Please cancel claims 8-11 and insert the following claims therefor:

8 ~~15.~~ A pharmaceutical composition as claimed in claim 1, wherein the effective amount is 20-400 mg ranitidine per 10 ml dose expressed as free base.

9 ~~16.~~ A pharmaceutical composition as claimed in claim 1, wherein the effective amount is 20-200 mg ranitidine per 10 ml dose expressed as free base.

10 ~~17.~~ A pharmaceutical composition as claimed in cliam 1, wherein the effective amount is 150 mg ranitidine per 10 ml dose expressed as free base.

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